

Comment

development, and smoking remains a scourge worldwide in our fight to improve health. For the ancient populations studied by Thompson and colleagues, infection is likely to provide the unifying explanation.⁹ A wealth of evidence points to a key role for inflammation in both circulatory and malignant processes.⁹ High levels of chronic infection and inflammation could have promoted cardiovascular lesion development and, although not being fatal for most, might have become so with the passage of time. These data confirm that atheroma has been a burden on the human circulation for centuries. Few are exempt, and as life expectancy lengthens owing to modern advances in public health and medicine, more will suffer its consequences unless urgent measures are taken to prevent its legacy.

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I have consulted for, and received fees for speaking from, Servier, Merck Serono, Novartis, and Daiichi-Sankyo.

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The Lancet journals welcome a new open access policy

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The often fractious debate about how best to make publicly funded research more widely accessible and useable has intensified over recent years and is gradually reaching a practicable resolution. For example, the UK's Finch report,¹ published last June by an independent group of academics, research funders, and publishers, clearly stated that the UK should embrace the transition to open access while recognising that it is important “to ensure that they [researchers] have effective and high-quality channels through which they can publish and disseminate their findings”.

Finch recommended that the research councils, together with other public sector bodies, should establish more effective and flexible arrangements to meet the cost of publishing in open access and hybrid journals. As a response, Research Councils UK (RCUK) has reviewed and revised its policy and, from April 1, 2013, new guidance comes into force. The latest revision, released on March 6, supports both “gold” open access (journal mediated, with authors retaining copyright under a CC-BY creative commons license after paying an article processing charge) providing immediate access,

and “green” open access (repository mediated, with authors posting the final accepted version of their paper without restriction of use) after an embargo period of 6 months for biomedical research.²

The Lancet journals welcome and support all efforts to make research more widely accessible and useable in ways that continue to sustain our broad mission to serve clinical medicine and global health. We will, in accordance with the new RCUK policy, offer either a “gold” open access choice with a creative commons license after payment of an article processing charge of US\$5000, or a “green” open access solution—where authors can deposit the final accepted version of their paper in any repository they choose 6 months after publication—for all RCUK-funded research papers submitted after April 1. In addition, for the “green” open access solution we will also make the published paper free to access on our websites 6 months after publication.

These options and a choice of three different creative commons licenses (CC-BY, CC BY-NC-SA, or CC BY-NC-ND) will be open to authors of all research papers supported by those funders with whom we currently have payment agreements.

Clearly, the debate on open access to publicly funded research is evolving and RCUK states that it “will undertake a comprehensive, evidence-based review of the effectiveness and impact of its Open Access policy in 2014”. Given the rapid pace of discussions on open access publication, the *Lancet* journals will continue to review how we can make all publicly funded research as accessible and useable as possible.

The Lancet Editors

The Lancet, London NW1 7BY, UK

- 1 Report of the Working Group on Expanding Access to Published Research Findings. Accessibility, sustainability, excellence: how to expand access to research publications. June 18, 2012. <http://www.researchinfonet.org/wp-content/uploads/2012/06/Finch-Group-report-FINAL-VERSION.pdf> (accessed March 18, 2013).
- 2 RCUK Policy on Open Access and Supporting Guidance. March 6, 2013. <http://www.rcuk.ac.uk/documents/documents/RCUKOpenAccessPolicyandRevisedguidance.pdf> (accessed March 18, 2013).

Expression of concern—Effect of tesofensine on bodyweight loss, body composition, and quality of life in obese patients: a randomised, double-blind, placebo-controlled trial

In 2008, *The Lancet* published a phase 2 study of tesofensine as an adjunct to a hypocaloric diet in the treatment of obesity.¹ The study was also published in *Ugeskrift for Læger*.² In 2011, The Danish Health and Medicines Authority decided to inspect completed trials at random. This study was among those selected and was inspected in November of that year. Concerns were expressed about two of the five sites where the trial was undertaken, and were brought to the attention of *The Lancet* in 2012 by the Article's corresponding author.

Three major points were raised by the inspection. First, Danish regulations require that informed consent is undertaken in its entirety by a medical practitioner, but in one site this duty had been delegated to non-medical personnel. Second, the integrity of blinding was questioned in an earlier inspection in 2007, and rebutted by the investigators. Third, the recording and assessment of adverse events by the contract research organisation was incomplete, because their staff did not consider as noteworthy the recurrence of events that

trial participants had experienced on occasions prior to the study. In particular, headache, migraine, stress, and depression were not reliably recorded in people who had experienced these conditions before enrolling in the trial. Therefore, the report concluded that “the overall side-effect profile that is...published in *The Lancet* is not in accordance with the actual course of the trial”.³

The aforementioned observations raise concerns about this study of which readers should be aware while the editors await further clarification on details from the Danish Health and Medicines Authority.

The Lancet Editors

The Lancet. London NW1 7BY, UK

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